

REMARKS

Claims 1-3, 6-10, and 21-22 are pending.

Applicants and the undersigned thank the Examiner for the telephone interview of December 6, 2007, in which the outstanding office action was discussed.

No issues of new matter should arise and entry of the amendment is respectfully requested.

I. Rejection under 35 U.S.C. §112, First Paragraph

Claims 1-3, 6-10, and 21-22 are rejected under 35 USC § 112, first paragraph, as lacking enablement and failing to comply with the written description requirement.

Applicants respectfully traverse the rejection and respectfully submit that the claims satisfy the requirements under 35 U.S.C. § 112, first paragraph.

The Examiner asserts that the rejections are based on the lack of recitation in the description of determining the therapeutic dosage and adjustment of therapeutic dosage for a patient in need of a nitrosated ACE inhibitor.

Applicants respectfully traverse this objection and submit that one skilled in the art would be able to determine the appropriate dose using standard clinical techniques as described in, for example, The Physician's Desk Reference by Goodman and Gilman, which is referred to in the specification on page 36, in the paragraph starting on line 25. As further described in the specification on pages 36-37, one skilled in the art would be able to determine and adjust the dose accordingly depending on patient profile, pharmacological considerations, route of administration, and other factors.

Applicants respectfully submit that, given the guidance provided in the specification and the knowledge available to the skilled artisan, one skilled in the art would readily be able to determine what a therapeutically effective amount of a particular nitrosated ACE inhibitor would be for the treatment of a particular vascular disease characterized by nitric oxide insufficiency in a patient in need thereof.

As evidence that those skilled in the art would readily be able to determine a therapeutically effective amount of a nitrosated ACE inhibitor given the guidance provided in the specification and the knowledge available to the skilled artisan, Applicants bring to the attention of the Examiner, PCT application WO 2004/110432, published after the filing date of

the present application. WO 2004/110432 is also directed to the nitrosated ACE inhibitors and pharmaceutical compositions thereof described in the present application, except for the different uses of treating cardiovascular and renal diseases, inflammatory processes, and ocular hypertension. In particular, WO 2004/110432 on page 42, lines 9-25, refers to the amount of NO-ACE inhibitor that should be used for an effective dose.

Applicants submit that, as shown by WO 2004/110432, others of skill in the art were working in the field of nitrosated ACE inhibitors and it was well within the purview of the skilled artisan, given the guidance provided in the present specification and the knowledge available in the art, to determine and adjust the therapeutic dosage for a patient in need of a nitrosated ACE inhibitor.

In response to the Examiner's argument that references such as The Physician's Desk Reference guides the dosage for nitrate salts such as isosorbide mono or dinitrate, and not nitrosated ACE inhibitors, Applicants respectfully submit that while these references may not refer to a specific recommended dosage for nitrosated ACE inhibitors, the references provide the standard clinical techniques that the skilled artisan will use to determine the appropriate patient dose. The skilled artisan would then be able to determine and adjust the dose accordingly depending on patient profile, pharmacological considerations, route of administration, and other factors, as described on pages 36-37 of the present specification and on page 42, lines 9-25 of WO 2004/110432.

In view of the above, Applicants respectfully submit that the claims satisfy the requirement under 35 U.S.C. § 112, first paragraph, and respectfully request that the rejection under this provision be withdrawn.

II. Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

The Commissioner is authorized to charge the fee for a Notice of Appeal and any other necessary fees, or credit any overpayments, to our Deposit Account No. 08-0219, under Order No. 0102258.00170US3 from which the undersigned is authorized to draw.

Application No. 10/692,724
Amendment dated December 19, 2007
After Final Office Action of September 20, 2007

Docket No.: 0102258.00170US3
Examiner: K.C. Srivastava
Group Art Unit: 1657

Respectfully submitted,

Dated: December 19, 2007

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